

In the United States Court of Federal Claims
OFFICE OF SPECIAL MASTERS
No. 21-2249V

ERIN O'LEARY,

Petitioner,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: August 5, 2024

Jonathan Joseph Svitak, Shannon Law Group, P.C., Woodridge, IL, for Petitioner.

Jamica Marie Littles, U.S. Department of Justice, Washington, DC, for Respondent.

DECISION DISMISSING CASE¹

On December 2, 2021, Erin O'Leary filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*² (the "Vaccine Act"). Petitioner alleges that she suffered a left shoulder injury related to vaccine administration ("SIRVA"), a defined Table Injury, after receiving an influenza ("flu") vaccine on October 27, 2020. Petition at 1, ¶ 2, 18.

However, the record in this case contains insufficient evidence to establish the pain onset within the timeframe required for a Table SIRVA, or even to support a causal link between Petitioner's left shoulder pain and the vaccination she received. See 42 C.F.R. § 100.3(a)XIV(B) & (c)(10)(ii) (2017) (requiring pain onset within 48 hours of vaccination);

¹ Because this Decision contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at <https://www.govinfo.gov/app/collection/uscourts/national/cofc>, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). **This means the Decision will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

² National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2018).

Althen v. Sec’y of Health & Hum. Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005) (three-pronged test for actual causation). And despite due opportunity, Petitioner has not provided the preponderant evidence needed to overcome these deficiencies. I therefore DENY entitlement in this case.

I. Relevant Procedural History

Along with her petition, Ms. O’Leary filed only a declaration signed under penalty of perjury as required by 28 U.S.C.A. § 1746. Exhibit 1. Over the subsequent 16-month period, she filed the medical records required by the Vaccine Act, as well as supporting signed declarations from her son and fiancée.³ Exhibits 2-12, ECF Nos. 6, 9, 14, 17, 21. On April 4, 2023, the case was activated and assigned to the “Special Processing Unit” (OSM’s adjudicatory system for resolution of cases deemed likely to settle). ECF No. 23.

Almost one year later, on March 15, 2024, Respondent stated that he intended to oppose compensation. Status Report, ECF No. 27. On April 29, 2024, he filed his Rule 4(c) Report setting forth his objections. ECF No. 28. Emphasizing Petitioner’s initial description of gradually increasing pain, report of recent exercise, and failure to mention the flu vaccine until almost 22 months post-vaccination (eight months after the petition’s filing), Respondent maintains Petitioner has not established the pain onset needed for a Table SIRVA. *Id.* at 4-5. He also insists that Petitioner has failed to provide adequate evidence of causation and thus, cannot prevail pursuant to a non-Table claim. *Id.* at 5-6.

On May 15, 2024, I issued an Order to Show Cause, allowing Petitioner a final chance to obtain and to file the evidence needed to support her allegations. ECF No. 30. After receiving an extension of time until July 22, 2024 (ECF No. 31), Petitioner has failed to provide any additional evidence.

The matter is now ripe for adjudication.

II. Applicable Legal Standards

Under Section 13(a)(1)(A) of the Act, a petitioner must demonstrate, by a preponderance of the evidence, that all requirements for a petition set forth in section 11(c)(1) have been satisfied. A petitioner may prevail on her claim if the vaccinee for whom she seeks compensation has “sustained, or endured the significant aggravation of any illness, disability, injury, or condition” set forth in the Vaccine Injury Table (the Table). Section 11(c)(1)(C)(i). According to the most recent version of the Table, a SIRVA is

³ These declarations also were signed under penalty of perjury as required by 28 U.S.C.A. § 1746. Exhibits 8-9.

compensable if it manifests within 48 hours of the administration of an influenza vaccine. 42 C.F.R. § 100.3(a)(XIV)(B). The specific criteria establishing a SIRVA are as follows:

Shoulder injury related to vaccine administration (SIRVA). SIRVA manifests as shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm. These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction. SIRVA is caused by an injury to the musculoskeletal structures of the shoulder (e.g. tendons, ligaments, bursae, etc). SIRVA is not a neurological injury and abnormalities on neurological examination or nerve conduction studies (NCS) and/or electromyographic (EMG) studies would not support SIRVA as a diagnosis (even if the condition causing the neurological abnormality is not known). A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:

- (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;
- (ii) Pain occurs within the specified time frame;
- (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and
- (iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 C.F.R. § 100.3(c)(10) (additional requirements set forth in the *Qualifications and Aids to Interpretations* ("QAI")). If a petitioner establishes that the vaccinee has suffered a "Table Injury," causation is presumed.

If, however, the vaccinee suffered an injury that either is not listed in the Table or did not occur within the prescribed time frame, petitioner must prove that the administered vaccine caused injury to receive Program compensation on behalf of the vaccinee. Section 11(c)(1)(C)(ii) and (iii). In such circumstances, petitioner asserts a "non-Table or [an] off-Table" claim and to prevail, petitioner must prove her claim by preponderant evidence. Section 13(a)(1)(A). This standard is "one of . . . simple preponderance, or

‘more probable than not’ causation.” *Althen*, 418 F.3d at 1279-80 (referencing *Hellebrand v. Sec’y of Health & Hum. Servs.*, 999 F.2d 1565, 1572-73 (Fed. Cir. 1993)). The Federal Circuit has held that to establish an off-Table injury, petitioners must “prove . . . that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury.” *Shyface v. Sec’y of Health & Hum. Servs.*, 165 F.3d 1344, 1351 (Fed. Cir. 1999). *Id.* at 1352. The received vaccine, however, need not be the predominant cause of the injury. *Id.* at 1351.

The Circuit Court has indicated that petitioners “must show ‘a medical theory causally connecting the vaccination and the injury’” to establish that the vaccine was a substantial factor in bringing about the injury. *Shyface*, 165 F.3d at 1352-53 (quoting *Grant v. Sec’y of Health & Hum. Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992)). The Circuit Court added that “[t]here must be a ‘logical sequence of cause and effect showing that the vaccination was the reason for the injury.’” *Id.* The Federal Circuit subsequently reiterated these requirements in its *Althen* decision. See 418 F.3d at 1278. *Althen* requires a petitioner

to show by preponderant evidence that the vaccination brought about her injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

Id. All three prongs of *Althen* must be satisfied. *Id.*

Finding a petitioner is entitled to compensation must not be “based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion.” Section 13(a)(1). Further, contemporaneous medical records are presumed to be accurate and complete in their recording of all relevant information as to petitioner’s medical issues. *Cucuras v. Sec’y of Health & Hum. Servs.*, 993, F.2d 1525, 1528 (Fed. Cir. 1993). Testimony offered after the events in questions is considered less reliable than contemporaneous reports because the need for accurate explanation of symptoms is more immediate. *Reusser v. Sec’y of Health & Hum. Servs.*, 28 Fed. Cl. 516, 523 (1993).

III. The Record as It Currently Stands

A. Medical Records

Prior to vaccination, Petitioner suffered from migraines, a sore throat, urinary tract infection, and ADHD.⁴ Exhibit 7 at 11-48. At a primary care provider (“PCP”) appointment for her annual physical on June 17, 2019, Petitioner reported a visit to an urgent care clinic after injuring her left knee and right ankle during a fall. *Id.* at 42.

Petitioner received the flu vaccine alleged as causal intramuscularly in her left deltoid at a CVS store on October 27, 2020. Exhibit 12 at 2. She next sought medical care almost three months later, in early January 2021, visiting her gynecologist to discuss contraception options. Exhibit 10 at 23. She returned twice in February 2021, for the insertion of an intrauterine device, commonly referred to as an IUD.⁵ Exhibit 10 at 14-33. There is no mention of left shoulder pain in the medical records from these visits.

On February 23, 2021, Petitioner visited her PCP, seeking to restart her ADHD medication but now also complaining of left shoulder pain “on going [for a] couple months [that was] not getting better.” Exhibit 7 at 57. Reporting “[n]o specific injury/trauma,” Petitioner stated that she “just felt a gradual pain and limited romn^[6] [sic],” adding that she “[h]a[d] been working out and doing a [Z]umba class.” *Id.* After reviewing x-rays taken (which showed degenerative changes),⁷ the PCP diagnosed Petitioner with adhesive capsulitis and prescribed physical therapy (“PT”). *Id.* at 61.

At her initial PT session a few days later, on February 26, 2021, Petitioner described progressively worsening left shoulder stiffness, soreness, and limited motion for the last three to four months. Exhibit 4 at 75. In response to the following question on the intake form - “How did your symptoms start?”, Petitioner wrote “gradually.” *Id.* at 85.

Over the subsequent four-month period, Petitioner attended 22 PT sessions. Exhibit 4 at 7-81. Assessed as having made objective improvement but slower progress due to a loss of insurance, she was provided a home exercise program and discharged on June 14, 2021. *Id.* at 13-14. There is no mention of the flu vaccine Petitioner received in October 2020 in any of these records.

⁴ ADHD stands for “attention-deficit hyperactivity disorder.” MEDICAL ABBREVIATIONS at 38 (16th ed. 2020).

⁵ IUD stands for “intrauterine device.” MEDICAL ABBREVIATIONS at 316.

⁶ ROM stands for range of motion. MEDICAL ABBREVIATIONS at 512.

⁷ The results of the radiology report shows “[m]ild degenerative disease of the left shoulder.” Exhibit 7 at 76-77.

Petitioner next sought medical care more than a year later, visiting her PCP for an annual physical on August 23, 2022. Exhibit 7 at 63-76. At this visit (which occurred more than eight months after the filing of the Petition in this case), Petitioner reported that her frozen shoulder had resolved after multiple rounds of PT and stretching. *Id.* at 70. For the first time, she attributed her condition to the flu shot. *Id.* This record also contains entries showing Petitioner had received COVID vaccines in her left deltoid (the shoulder at issue herein) on March 25 and 16, 2021. *Id.* at 64.

B. Later Provided Evidence

In her declaration, signed on August 25, 2021, and filed with the Petition in December 2021, Petitioner asserted that her left shoulder pain began “a few hours after [she] received the influenza vaccine at CVS.” Exhibit 1 at ¶ 6. After attempting to treat her condition with over-the-counter pain medication, stretching, and ice packs, she sought an appointment with her PCP in January 2021. *Id.* at ¶ 7. Petitioner insisted that she informed both her PCP and the physical therapist that her pain “started after getting the influenza vaccine on October 27, 2020.” *Id.* at ¶ 8; *accord. Id.* at ¶ 9.

In his declaration, signed on June 15, 2022, Petitioner’s son (who lives with Petitioner) recalled observing limitations in his mother’s range of motion and assisting her reaching for items on October 27, 2020. Exhibit 8 at ¶ 6. He stated that Petitioner continued to need assistance thereafter, adding that he “still observe[s] her doing routine stretches and using a heating pad and ick packs when she needs to.” *Id.* at ¶ 8.

In his declaration, signed a few months later, on September 7, 2022, Petitioner’s fiancée (who also lives with Petitioner) echoed the assertions made by her son. *Compare* Exhibit 8 *with* Exhibit 9. He also asserted that “[a]s of today, [he] continue[d] to witness Erin in noticeable pain and discomfort due to her left shoulder injury.” *Id.* at ¶ 10.

IV. Analysis

All evidence from prior to the Petition’s filing supports a gradual, rather than acute, pain onset beginning sometime in late Fall 2020. When first seeking treatment, Petitioner described gradual left shoulder pain beginning a couple of months earlier, placing onset around late November 2020. Exhibit 7 at 57. Later, at her first PT session, she estimated her pain began three to four months earlier, placing onset closer to vaccination – in late October or November 2020. Exhibit 4 at 75. However, Petitioner again described the onset of her pain as gradual, and (importantly) failed to mention the flu vaccine she received. *Id.* at 75, 85.

In fact, there is *no mention of the flu vaccine* in any of the medical records related to the treatment Petitioner received. And, at her initial PCP visit, Petitioner theorized that her shoulder pain may be due to working out and participating in Zumba classes. Exhibit 7 at 57. Furthermore, while attending PT (late February through mid-June 2021), Petitioner received COVID vaccines in her left deltoid (in March and April). Thus, all information provided in the contemporaneously created medical records supports a more gradual injury, likely due to the degenerative changes seen on x-rays and overuse from exercise.

Petitioner did not attribute her left shoulder pain to the flu vaccine she received until she finished PT, retained Petitioner's counsel, and began preparing her vaccine claim. See Petition at 1; Exhibit 1.⁸ And she did not mention the flu vaccine as a potential source of her pain to any medical provider until almost one year thereafter (August 23, 2022), after her symptoms had resolved. See Exhibit 7 at 70 (medical record from annual physical on August 23, 2022).

In her declaration, Petitioner claimed that her pain began with a few hours of vaccination, and that she attributed her symptoms to the flu vaccine when speaking to both her PCP and physical therapist. Exhibit 1 at ¶¶ 6, 8-9. However, these later-provided assertions run counter to the information contained in the contemporaneously created medical records. See *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993); *Lowrie v. Sec'y of Health & Hum. Servs.*, No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005) (stating that medical records which are clear, consistent, and complete should be afforded substantial weight). Even supported by the declarations from her son and fiancée, Petitioner's assertions are not sufficient to counter the evidence presented by the contemporaneously created medical records which supports a later gradual pain onset, more likely attributable to degenerative changes and overuse while exercise.

These deficiencies were pointed out to Petitioner, and she was given the chance to address them by supplementing the evidentiary record. She has failed to do so, and therefore the evidence preponderates against her claim.

Conclusion

To date, and despite ample opportunity, Petitioner has failed to provide preponderant evidence to support her allegation of a left shoulder injury that meets the definition for a Table SIRVA or was caused by the flu vaccine she received on October 27, 2020. Petitioner was informed that failure to provide preponderant evidence to support

⁸ Although not filed until December 2021, the Petition is dated August 25, 2021. Petition at 1. And Petitioner's declaration was signed the same day, on August 25, 2021. Exhibit 1 at 3.

her claim would be treated as either a failure to prosecute this claim or as an inability to provide supporting documentation for the claim. Accordingly, this case is DISMISSED. The Clerk of Court shall enter judgment accordingly.⁹

IT IS SO ORDERED.

s/Brian H. Corcoran

Brian H. Corcoran
Chief Special Master

⁹ Pursuant to Vaccine Rule 11(a), entry of judgment can be expedited by the parties' joint filing of notice renouncing the right to seek review.